DEVELOPMENT OF BION™ TECHNOLOGY FOR FUNCTIONAL ELECTRICAL STIMULATION: BIDIRECTIONAL TELEMETRY

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Abstract - **BIONs™ are individually addressable, single channel electrical interfaces that can be injected into one or more muscles through a 12-gauge hypodermic needle. They receive power and command signals from an externally worn RF transmission coil and generate stimulation pulses to activate motor units. In order to reanimate useful function in a paralyzed limb, it is necessary to incorporate sensors and back telemetry to provide voluntary control and sensory feedback signals. We describe and compare several sensing modalities and bi-directional telemetry schemes that have been developed and are being evaluated to support these requirements.**

Keywords **- neural prostheses, electrical stimulation, implants, telemetry, sensors**

I. Introduction

BIONs (BIOnic Neurons) are modular, microminiature implants (Figure 1), each of which provides a long-term, wireless interface between an electronic controller and a neural function in the body [1]. An extracorporeal transmitter coil is placed over a region of the body that contains one or more BIONs, which receive power and command signals by inductive coupling. The first generation of this technology (BION1) produces stimulation pulses with controlled current (0-30mA) and duration (4-512µs). BION1 implants have undergone extensive preclinical testing [8]. They are being used in two ongoing clinical trials that study the therapeutic effects of electrically induced exercise to prevent and reverse disuse atrophy in patients with stroke and osteoarthritis [2].

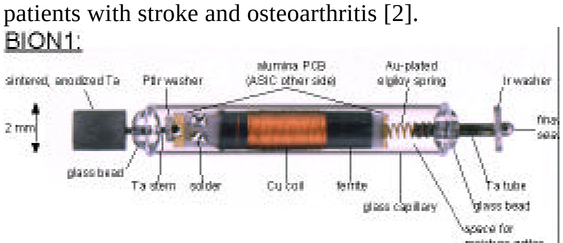

Figure 1. *Main components and hermetic packaging scheme for a BION1 implant*

Application of this technology to produce functional movements of a paralyzed limb will require a sophisticated control system that must be driven by two types of data from the patient: 1) command signals, probably derived from the electrical and/or mechanical activity of those muscles that are still under voluntary control; and 2) feedback signals regarding the progress of the movement that is being produced by the functional electrical stimulation (FES) of the paralyzed muscles. The BION2 system now under development may need to accommodate up to 64 sensing and stimulation channels deployed in various sites distributed over the limb.

II. Sensing

We have identified three sensing modalities that seem to be functionally useful and technologically feasible within the constraints of size and power implicit in the injectable BION package [9]:

- Myoelectric signals (EMG) will be detected by the existing electrodes and amplified, digitized and processed within the BION2 implant prior to outward transmission. These data will be useful as command signals from voluntarily activated muscles and as feedback to quantify muscle recruitment by FES.
- Accelerometers based on MEMS technology and capacitive charge detection appear to be feasible to miniaturize so as to fit into a slightly larger version of the BION1 package. These will provide information about limb orientation with respect to gravity and translational acceleration.
- Kinesthesia will be provided by the BIONic equivalent of muscle spindles, the naturally occurring proprioceptors that sense muscle length and velocity, used by the nervous system to compute body posture.

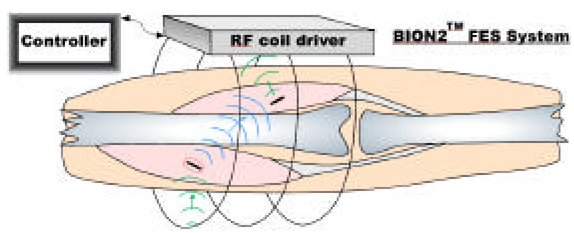

Figure 2. *BIONic muscle spindle based on measuring mutual inductive coupling between implants.*

One attractive option for creating a BIONic muscle spindle is illustrated in Figure 2. The external controller sends a command to one BION2 implant, causing it to emit an RF signal. Another BION2 has been instructed previously to detect and quantify the amplitude of that RF signal. The second implant is then commanded to transmit data regarding the signal strength it recorded, which depends on the relative distance and orientation between

Report Documentation Page

Report Date	Report Type	Dates Covered (from... to)
25OCT2001	N/A	-

Title and Subtitle Development of Biona Technology for Functional Electrical Stimulation: Bidirectional Telemetry	**Contract Number**
	Grant Number
	Program Element Number
Author(s)	**Project Number**
	Task Number
	Work Unit Number
Performing Organization Name(s) and Address(es) A.E. Mann Institute for Biomedical Engineering, University of Southern California Los Angeles, CA 90089	**Performing Organization Report Number**
Sponsoring/Monitoring Agency Name(s) and Address(es) US Army Research Development & Standardization Group (UK) PSC 802 Box 15 FPO AE 09499-1500	**Sponsor/Monitor's Acronym(s)**
	Sponsor/Monitor's Report Number(s)

Distribution/Availability Statement
Approved for public release, distribution unlimited

Supplementary Notes
Papers from the 23rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society, October 25-28, 2001, held in Istanbul, Turkey. See also ADM001351 for entire conference on CD-ROM., The original document contains color images.

Abstract

Subject Terms

Report Classification unclassified	**Classification of this page** unclassified
Classification of Abstract unclassified	**Limitation of Abstract** UU

Number of Pages
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the two implants. Changes in the posture of the limb tend to be accompanied by changes in the relative positions of the muscles that operate the joints. Thus, the mutual coupling between all possible pairs of implants in the muscles could be interpreted by a neural network or look-up table to determine the most likely current posture of the limb.

III. POWER TRANSMISSION

Because the BIONs contain no batteries, all of their electrical power must be derived from the externally generated RF field. Transcutaneous magnetic inductive coupling has been used widely as a simple method for power and data transfer to implanted devices. A receiver coil inside the implanted device is magnetically coupled via a radio-frequency magnetic field to an external transmitting coil, thus forming an air-tissue-core transformer that transfers both power and data to the implant.

The amount of the magnetic field linked with the implant, relative to the amount of magnetic field produced by the transmitting coil, is called the coefficient of coupling. It is a measure of the efficiency of the inductive link; substantial prior work has been devoted to its optimization [3-7,12,16]. Heetderks [6] analyzed transcutaneous inductive links that used sub-millimeter sized solenoidal receiver coils, similar to that used in the BION. His predictions for mismatched coils such as in the BION system agree with our measured coefficient of about 0.05, a very inefficient link.

This limitation has been overcome through the use of Class E amplifiers with very high Q (~125), which allow high field strengths to be generated with minimal power dissipation [9,11,13,14]. As part of our development of these transmitters we devised a method of closed-loop control that keeps the Class-E circuit operating at the highest efficiency regardless of changes in the transmitter coil placement, shape, or proximity to external metal objects.

IV. COMMAND TRANSMISSION

High Q power oscillators are inherently difficult to modulate in order to transmit data because bandwidth is inversely proportional to Q. They also tend to become less efficient at higher carrier frequencies because of non-ideal behavior of both passive and active components. In our emerging design for the BION system, this motivates reduction of the carrier frequency from its present 2MHz to 500KHz. Unfortunately, this exacerbates the problem of transmitting sufficient data to command and monitor a large number of implants at a reasonable rate.

We have developed a method of modulation of the closed-loop Class-E transmitter that allows for extremely high data rates, up to the transmitter frequency itself, with almost no additional power requirements [10,15]. We accomplish this by producing 100% on-off modulation of the transmitter power carrier. This method, known as "suspended-carrier modulation" permits the transmitter to be "on" for any integer number of transmitter cycles, but to be turned "off" for an arbitrary time - from fractions of a cycle to many thousands of cycles. This allows the data rate to approach the carrier frequency. Suspended-carrier modulation can be used readily in many different data encoding schemes. An example of a transmitter operating in the suspended-carrier mode is shown in Figure 3.

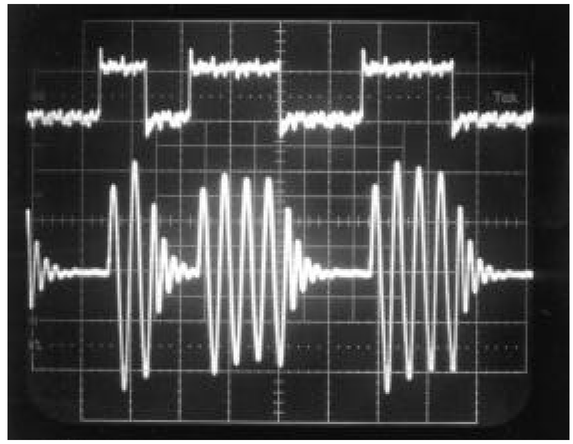

Figure 3. *Suspended carrier waveform. Upper: Modulation signal. Lower: Transmitter coil current at 1A/div., 5usec/div.*

In order to use the suspended-carrier technique for forward telemetry, the implant circuitry must be able to detect the rapid drop-outs of the transmitter power carrier. A simplied circuit diagram which illustrates our approach to this problem is shown in Figure 4. When the transmitter is turned off, the microcoil conducts through the recitifier diode for one or possibly two half cycles of the transmitter frequency due to energy stored within the implant's resonant circuit. Once the microcoil voltage has dropped below the level at which the rectifer diode will conduct, the resonant circuit reverts to a high-Q circuit. The microcoil voltage continues to "ring" for many cycles, limited only by the loss of the microcoil itself. This ringing voltage is easily detectable to generate the implant's clock. The cessation of rectifier current can be sensed, and used to detect the presence or absence of the transmitter current. Thus, we are able simultaneously to retain the implant's clock and to sense the data encoded within the suspended-carrier modulated transmitter. We have already tested prototype integrated circuits that use this method of clock and data detection.

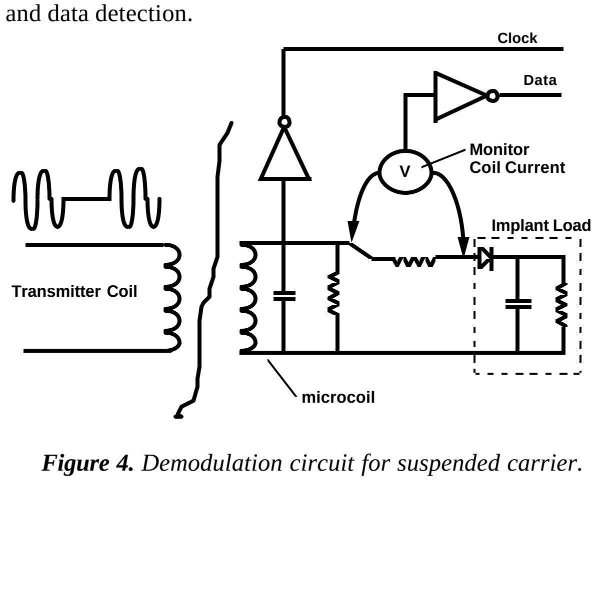

Figure 4. *Demodulation circuit for suspended carrier.*

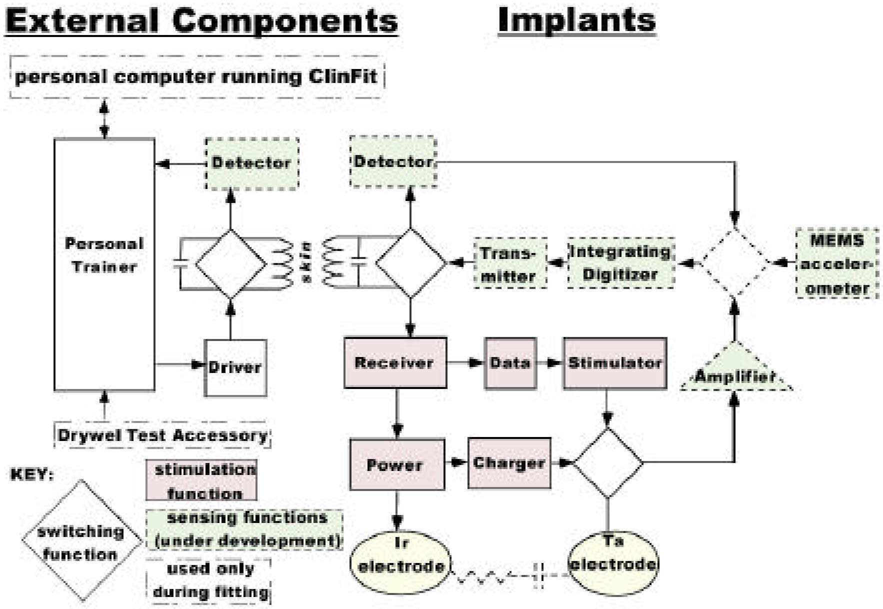

Figure 5. *Schematic system diagram for bi-directional telemetry using one external and one internal coil for all power and data transmission. The incoming carrier provides power and command data for stimulation (existing) and various sensing modalities (under development). The outgoing data from the sensors is encoded on an outgoing carrier that must be detected by the external coil and decoded to provide feedback information for the external control system (Personal Trainer containing a microprocessor running a control algorithm loaded into it as part of the fitting process).*

V. BIDIRECTIONAL TELEMETRY

Detection of an outward telemetry signal from these tiny implants is inherently problematic, although it has been achieved in commercial transponders used to identify animals. There are two fundamental problems:
1) There is little room for separate components to support each direction of telemetry.
2) The power carrier produced by the transmitter is typically one billion times greater in magnitude than the reverse telemetry signal.
The desired bi-directional system is illustrated schematically in Figure 5.

There are two basic systems used for reverse telemetry from microimplants: full duplex and half duplex.

In the full duplex system, the reverse telemetry signal is placed on a data subcarrier that is an integer submultiple of the power carrier and is transmitted back to the extracoporeal receiver while the power carrier is present. That is, no significant energy is stored in the microimplant so that the transmitter must continue to power the implant during the period of reverse telemetry. As such, the receiver must have a means to reject the relatively large transmitter signal from the relatively weak reverse telemetry signal. This approach is depicted in Figure 6, below.

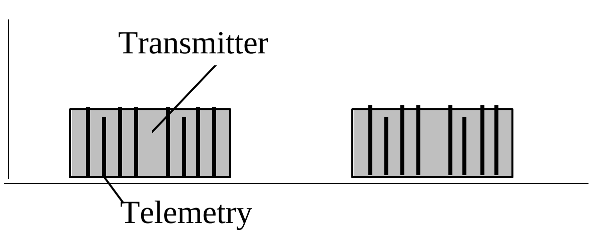

Figure 6. *Full duplex bidirectional telemetry*

In the half duplex system, the power carrier is used to store energy within the microimplant. Once a sufficient level of energy storage has been achieved, the transmitter is turned off. The cessation of the transmitter is used to trigger the microimplant to begin its reverse telemetry. A local oscillator is modulated by the telemetry data. The stored energy within the microimplant is used to power the implant's circuitry during the telemetry period. This approach is depicted in Figure 7, below.

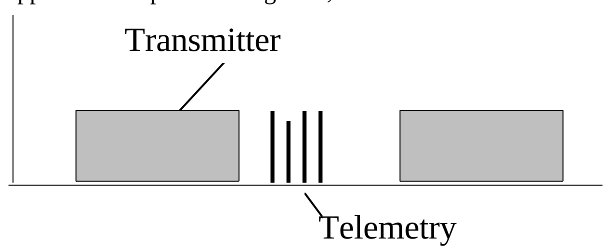

Figure 7. *Half-duplex bidirectional telemetry*

The advantage of the full duplex system stems from its simplicity within the microimplant. The data subcarrier is conveniently generated by integer division of the clock derived from the transmitter power carrier. The subcarrier current in the implant's coil is easily generated by synchronous loading of the implant coil. Because little-to-no energy storage within the implant is required, the number of discrete components within the microimplant is minimized. There are two main disadvantages of the full duplex system. First, continuous presence of the power carrier may interfere with noise-sensitive functions such as bioelectric sensing. Second, the transmitter/receiver must contain either complex rejection circuitry or canceling magnetic assemblies to remove the power carrier from the input to the receiver, or else the reverse telemetry signal will be hopelessly obscured.

The advantage of the half duplex system system is that the power carrier is turned off during all time periods in which data is collected or reverse telemetry is sent. This eliminates any possible interference with sensors and greatly simplifies the transmitter/receiver circuitry. Choosing the data carrier to be at the same frequency as the power carrier permits the optimization of the magnetic link at a single frequency. There are two main disadvantages of the full duplex system. First, the energy storage capacitor may be difficult to fit into the microminiature implant. Second, the integrated circuit design is more complex because a local oscillator within the implant is required to generate the data carrier. This oscillator must be combined with the rectification circuitry in the front-end of the implant's integrated circuit.

VI. Discussion

Presently we are exploring both the full and half duplex method for reverse telemetry in the BION2 family of devices. Preliminary simulations indicate that for the typical displacement between the transmitter and microimplant coils, it is feasible to trap the outgoing subcarrier of the full-duplex system within a demodulator circuit connected directly to the transmitter coil. This would be highly advantageous because only one coil element would be needed to be worn on the body. In this system it may still be required to suspend the carrier during periods of data collection to avoid RF noise, but the actual telemetry could take place while the transmitter is providing power.

We are also considering the half-duplex approach, using the suspended-carrier technique to turn off the transmitter during periods of reverse data transmission. Presently we are preparing to fabricate an integrated circuit design that will allow us to decide which approach to use.

VII. Conclusion

Bidirectional telemetry systems need to be designed and optimized as complete systems. This is particularly the case when such systems are constrained by conflicting demands for power transmission, data rate and physical size in implanted and portable applications such as functional electrical stimulation.

Acknowledgment

Funded by NIH Grant #R01-HD39099 and the A.E. Mann Institute for Biomedical Engineering

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